

Canadian Embassy



Ambassade du Canada

501 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

July 23, 1999

Mr. Philip L. Chao
Office of Policy, (HF-23)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
BY FAX (301) 443-6906

Dear Mr. Chao,

RE: Foreign Establishment Registration and Listing
Docket No. 98N-1215

On May 14, 1999, the Food and Drug Administration published a proposed rule that would, *inter alia*, require all foreign establishments who export medical devices, animal and human drugs to the United States to identify a US-designated agent who would serve as the firm's "official correspondent" in communications with your agency.

This proposed requirement could present significant cost and compliance burden to small and medium size establishments in Canada, many of whom have longstanding commercial relationships in the United States marketplace. The Government of Canada, therefore, is currently in the process of ensuring that affected Canadian establishments are aware of this notice. In order to provide them and the Canadian Government with the opportunity to prepare informed comments, we would ask for an extension of the comment period. In the interim, please do not hesitate to contact Birgit Matthiesen of my staff at 202-682-7747 with any questions you may have.

Yours sincerely,

Colleen Swords

Colleen Swords
(Minister-Counsellor)
Economic and Trade Policy

98N-1215

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